IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Andrew T. Berry (AB-4170)
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
973-639-2097
Attorneys for Plaintiffs

Of Counsel:
Robert L. Baechtold (RB-6866)
Joseph M. O'Malley, Jr. (JO-7733)
Herbert W. Rea (HR-3047)
Karen M. Stoffan (KS-1822)
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
(212) 218-2100

Attorneys for Plaintiffs
Altana Pharma AG and Wyeth

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| ALTANA PHARMA AG, and WYETH<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES, LTD.,<br><br>Defendants. | CIVIL ACTION NO.___ |

**COMPLAINT FOR PATENT INFRINGEMENT**

1. Altana Pharma AG is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

2. Wyeth is a Delaware corporation with its headquarters located at Five Giralda Farms, Madison, NJ 07940.

3. Altana Pharma AG is at times referred to hereinafter as "Altana."

4. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 650 Cathill Road, Sellersville, Pennsylvania 18960, its corporate headquarters at 1090 Horsham Road, PO Box 1090, North Wales, Pennsylvania 19454-1090, and places of business at 1801 River Road, Fairlawn, New Jersey 07410; 8-10 Gloria Lane, Fairfield, NJ 07004; 209 McLean Boulevard, Paterson, NJ 07504; and 140 Hoper Ave, Waldwick, NJ 07463.

5. Upon information and belief, Teva Pharmaceuticals Industries, Ltd. ("Teva Industries") is an Israeli corporation having its principal place of business at 5 Bazel, P.O.B. 3190, 49131 Petah Tikva, Israel.

6. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries, and the two have common officers and directors.

7. Upon information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, the assistance of and at least in part for the benefit of, Teva Industries.

8. Teva USA and Teva Industries are at times referred to hereinafter collectively as "Teva."

## JURISDICTION AND VENUE

9. Teva USA sells various products and does business throughout the United States including this District.

10. Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold and used, including by Teva USA, throughout the United States, including this District.

11. This action arises under the patent laws of the United States of America and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

## CLAIM FOR RELIEF

12. Wyeth Pharmaceuticals Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application ("NDA"), No. 20-987, by which the United States Food & Drug Administration ("USFDA") first granted approval for 20 mg and 40 mg delayed-release tablets including the active ingredient pantoprazole sodium. The pantoprazole sodium delayed-release tablets described in the NDA are prescribed for gastro-intestinal disorders associated with acid secretion. Wyeth and Altana co-promote these tablets in the United States under the tradename "PROTONIX®."

13. Altana is the owner of United States Patent No. 4,758,579 ("the '579 patent"), which was duly and legally issued on July 19, 1988, and discloses and claims certain compounds useful for inhibiting gastric acid secretion, including pantoprazole sodium, the active ingredient of PROTONIX®.

14. Wyeth is the exclusive licensee of the '579 patent in the United States.

15. A copy of the '579 patent is attached as Exhibit A.

16. Upon information and belief, Teva filed in the USFDA an Abbreviated New Drug Application ("ANDA") including a certification with respect to the '579 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell pantoprazole sodium delayed-release tablets, eq. 20 mg and 40 mg base, prior to the expiration of that patent.

17. Upon information and belief, the pantoprazole sodium drug substance referenced in the Teva ANDA, and the pantoprazole delayed release tablets that are the subject of the Teva ANDA are to be manufactured by Teva Industries.

18. On or about April 6, 2004, Teva sent a notice to Altana and Wyeth Pharmaceuticals, Inc. in which Teva represented that it had filed an ANDA for pantoprazole sodium, including the certification with respect to the '579 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

19. Altana received notice of the Teva certification on or about April 8, 2004.

20. Wyeth Pharmaceuticals, Inc. received notice of the Teva certification on or about April 7, 2004.

21. Because Teva seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug claimed in the '579 patent before its expiration, Teva has infringed the '579 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

22. Altana and Wyeth are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration date for the

'579 patent, or any later expiration of exclusivity for the '579 patent to which Altana and/or Wyeth is or becomes entitled.

23. Upon information and belief, Teva was aware of the existence of the '579 patent and was aware that the filing of its ANDA and certification with respect to the '579 patent constituted an act of infringement of that patent.

24. Teva's statement of the factual and legal bases for its opinion regarding the invalidity of the '579 patent is devoid of an objective good faith basis in either the facts or the law.

25. Teva's infringement of the '579 patent was and is willful.

26. This case is an exceptional one, and Altana and Wyeth are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

27. Plaintiffs request that:

a. Judgment be entered that Defendants have infringed the '579 patent by submitting the aforesaid ANDA;

b. Judgment be entered that Defendants' infringement of the '579 patent was and is willful, and Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. To the extent Defendants have committed any acts with respect to the compounds claimed in the '579 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiffs be awarded damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

d. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compounds as claimed in the '579 patent;

e. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 77-056 be a date that is not earlier than the expiration date for the '579 patent, or any later expiration of exclusivity for the '579 patent to which Plaintiffs are or become entitled; and

f. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: 5/20/04

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**CERTIFICATE PURSUANT TO L. CIV. R. 11.2**

I hereby certify that, to the best of my knowledge, this is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: 5/20/04

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